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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,109	10/09/2001	Roger J. Greenwald	ML-0492DIV	6851

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EXAMINER	
FINEMAN, LEE A	

ART UNIT	PAPER NUMBER
2872	

DATE MAILED: 04/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/973,109	GREENWALD ET AL.	
	Examiner	Art Unit	
	Lee Fineman	2872	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-11 and 21-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-11,21,23-26 and 28-50* is/are rejected.

7)☒ Claim(s) *22 and 27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 Oct. 2001 & 08 Jan. 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *see continuation*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Information Disclosure Statement(s) Mail Date: 1/22/02, 10/11/02, 1/8/04

DETAILED ACTION

This Office Action is in response to an amendment filed 8 January 2004 in which claims 9, 21-22 and 25-33 were amended and claims 36-50 were added. Claims 9-11 and 21-50 are pending.

Information Disclosure Statement

1. Applicant requested confirmation of that all references from Information Disclosure Statements (filed 22 January 2002 and 11 October 2002) as well as newly submitted Information Disclosure Statement (filed 8 January 2004) have been considered. The examiner is including copies of all three Information Disclosure Statements with this action.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 9-10 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly, U.S. Patent No. 3,510,194 in view of Ornstein et al., U.S. Patent No. 4,545,831 and Takimoto et al., U.S. Patent No. 5,843,674.

Regarding claims 9 and 21, Connelly discloses an apparatus (fig. 4) for imaging a specimen having a refractive index comprising a tray (42) upon which a specimen (41) is disposed; a means for clamping/clamp (44) said specimen to keep the specimen stationary

(column 3, lines 50-51) wherein the means for clamping is a finger; and optics (column 3, line 56, in so far as a microscope has optics) directed toward said specimen through a cover (40). Connelly discloses the claimed invention except for the specimen being excised tissue of at least several millimeters in thickness, the optics directed through a window in said tray, and the tray containing an immersion media having a refractive index matching the index of said excised tissue. Excised tissue, of varying thickness including several millimeters, is well known in the art as a specimen to be examined in a microscope. For example, Takimoto et al. teaches examining excised tissue specimens of at least several millimeters in thickness (column 15, lines 50-55) through a microscope (column 16, line 15). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to put any well-known specimen including excised tissue into the system of Connelly to determine that specimen's microscopic properties. Further, Ornstein teaches in fig. 4B a specimen (9), which is excised tissue, within an immersion media (18 and 27 – which are both curable polymer mediums with the same refractive index) having a refractive index matching the refractive index of the specimen (column 5, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add an immersion medium to the system of Connelly to match the index of refraction of the specimen as suggested by Ornstein to give a very high quality image (column 5, lines 31-33, Ornstein). Ornstein further teaches the specimen on a clear tray (16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the tray of Connelly transparent (a window) so the specimen against it can be viewed by inverted microscope systems.

4. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, and further in view of Tomimatsu, U.S. Patent No. 5,870,23.

Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, disclose the claimed invention except for discloses a means disposed between said tray and said optics which presents a medium between said tray and said optics optically coupling said optics to said tray. In fig. 2, Tomimatsu teaches a means (14) disposed between said tray (12) and said optics (13) which presents a medium (14a) between said tray and said optics optically coupling said optics to said tray (column 3, lines 31-34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the means of Tomimatsu to the system of Connelly in view of Ornstein et al. and Takimoto et al. to correct for spherical aberrations (column 2, lines 44-47).

5. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, and further in view of Atwood et al., U.S. Patent No. 5,675,700.

Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, disclose the claimed invention except for having indicia applied to said tray for identification of said specimen disposed therein. Atwood et al. discloses indicia applied to a tray (figs. 1 and 2) for identification of the specimen disposed therein. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tray of Connelly in

view of Ornstein et al. and Takimoto et al. to help keep the specimens in order and easily tracked.

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, and further in view of Foote, U.S. Patent No. 1,002,910.

Connelly in view of Ornstein et al. and Takimoto et al., as applied to claim 9 above, disclose the claimed invention except for wherein said clamping means has a mesh or membrane capable of holding said specimen upon said tray. Foote discloses a clamping means that has a mesh (10, column 2, lines 78-83, where the pliable sheet is cloth) or membrane (10, column 2, lines 78-83, where the pliable sheet is paper) capable of holding a specimen upon a tray (fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the tray of Tomimatsu in view of Connelly and Ornstein et al. and Takimoto et al. to make the clamping means a mesh or a membrane as suggested by Foote to be easily adaptable for clamping specimens of various shapes and sizes.

7. Claims 25-26 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Tomimatsu.

Regarding claims 25-26 and 30-32, Connelly discloses a holder and method for imaging a specimen comprising the steps of providing a container (figs. 1 and 2) having a surface (10) for placement of said specimen (23); restraining said specimen in said container against said surface to keep said specimen stationary and against said surface (column 3, lines 50-51) wherein said

restraining step is carried out with the aid of a clamping member (21) located within said container (fig. 1), which comprises a finger, extending into said container; and imaging said specimen through the cover (13) of said container (column 3, lines 62-63). Connelly discloses the claimed invention except for the specimen being excised tissue and imaging is through said surface or a window in which the specimen is against. Tomimatsu teaches a microscopic system (figs. 2,4,6) wherein a specimen (12) in a transparent container (11) is imaged on either side of the container, which are windows. It would have been obvious to one of ordinary skill in the art at the time the invention was made to make both container surfaces of Connelly transparent, or windows, to image the specimen with different microscopy systems. Therefore the specimen of Connelly would be against the surface to be imaged. Further, Official Notice is taken that tissue, including excised tissue, are common specimens for microscopic examination and it would have been obvious to one of ordinary skill in the art at the time the invention was made to view excised tissue with this system to determine the tissue's microscopic properties.

It is noted as directed by the MPEP 2144.03 that if the applicant does not seasonably traverse the well-known statement during examination, then the object of the well-known statement is taken to be admitted prior art. *In re Chevenard*, 139 F.2d 71, 60 USPQ 239 (CCPA 1943). As such, the examiner's official notice statement above is now held to be admitted prior art.

Regarding claim 33, Connelly further discloses wherein said restraining step further comprises the step of biasing each of said fingers to restrain said tissue against said surface (in so far as each finger will be moved, or biased, slightly when pressing against the sample).

8. Claims 28-29 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Tomimatsu, as applied to claims 25 and 30 above, and further in view of Foote, U.S. Patent No. 1,002,910.

Connelly in view of Tomimatsu, as applied to claims 25 and 30 above, disclose the claimed invention except for wherein said clamping member/restraining step has a mesh or membrane capable of holding said specimen against said surface/window. Foote discloses a clamping member/restraining step that has a mesh (10, column 2, lines 78-83, where the pliable sheet is cloth) or membrane (10, column 2, lines 78-83, where the pliable sheet is paper) capable of holding a specimen against a surface/window (fig. 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the surface/window of Connelly in view of Tomimatsu to make the clamping member a mesh or a membrane as suggested by Foote to be easily adaptable for clamping specimens of various shapes and sizes.

9. Claims 36-42 and 45-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Tomimatsu, as applied to claim 30 above, and further in view of Saulietis, U.S. Patent No. 5,367,401 and Ornstein.

Connelly in view of Tomimatsu disclose the claimed invention except for using a plurality of the containers of Connelly in view of Tomimatsu, to image different specimens wherein each container is positioned in an imaging path and wherein each container includes liquid having a refractive index matching the refractive index of the specimen and also serves as a tissue preservative or fixative and wherein imaging occurs several millimeters from the surface

of the specimen. Saulietis teaches wherein a plurality of containers is used for imaging different samples and wherein each container is positioned in an imaging path (figs. 1 and 2). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a plurality of the containers of Connelly in view of Tomimatsu as suggested by Saulietis to image many different specimens, including any excised tissue like from a kidney, a liver, or a cervix. Ornstein teaches in fig. 4B a specimen (9), which is excised tissue, within an immersion media (18 and 27 – which are both curable polymer mediums with the same refractive index) having a refractive index matching the refractive index of the specimen (column 5, lines 23-26). It would have been obvious to one of ordinary skill in the art at the time the invention was made to add an immersion medium to the plurality of containers to match the index of refraction of the each specimen as suggested by Ornstein to give a very high quality image (column 5, lines 31-33, Ornstein). Therefore the interface between the two materials "disappears" so imaging is inside the specimen and not the specimen surface (see Ornstein, column 5, lines 23-31). Tomimatsu further teaches wherein the container (11) has a liquid immersion medium (22a), which also serves as a tissue preservative (in so far as the tissue is protected while in the liquid). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the immersion medium of each container liquid as suggested by Tomimatsu to speed up specimen preparation time because curing is not necessary.

10. Claims 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Connelly in view of Tomimatsu, Saulietis and Ornstein, as applied to claim 42 above, and further in view of Murakami et al., U.S. Patent No. 5,296,963.

Connelly in view of Tomimatsu, Saulietis and Ornstein, as applied to claim 42 above, disclose the claimed invention except for wherein the imaging is made by a laser beam. Murakami et al. teaches a microscope (fig. 2) using a laser (1) for imaging specimen (5). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a laser microscope like Murakami's to image the specimen within the container of Connelly in view of Tomimatsu, Saulietis and Ornstein to be able to more accurately image specific small sections of the specimen.

Allowable Subject Matter

11. Claims 22 and 27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: Claims 22 and 27 have allowable subject matter over the prior art for at least the reason that the prior art fails to teach and/or suggest wherein a spring biases the finger to restrain/hold said excised tissue against said window/tray as set forth in the claimed combination.

Connelly discloses an apparatus (fig. 4) for imaging a specimen comprising a tray (42) upon which a specimen (41) is disposed; a means for clamping/clamp (44) said specimen to keep the specimen stationary (column 3, lines 50-51) wherein the means for clamping is a finger but does not have suggest wherein a spring biases the finger to restrain/hold said specimen against said window/tray as claimed.

Response to Arguments

13. Applicant's arguments, see page 12, lines 6-27, page 14, lines 21-30, page 15, lines 12-14, and page 16, lines 15-24, filed 8 January 2004, with respect to claims 25-27 and 30-33 and the Atwood reference have been fully considered and are persuasive. The 102 rejection of claims 25-27 and 30-33 has been withdrawn.

14. Applicant's arguments filed 8 January 2004 have been fully considered but they are not persuasive.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). With respect to claims 9 and 21, the tray system of Connelly can be used with any specimen to examine that specimen's microscopic properties, and Ornstein is used for teaching that matching the refractive index of

specimens, like tissue specimens, with the refractive index of an immersion medium give a very high quality image (column 5, lines 31-33, Ornstein). Further, the refractive index matching material is used to match the refractive indices of both materials, such that the interface between the two materials "disappears" so one can image the material inside the specimen and not the specimen surface. With respect to claims 25-26 and 30-33, Tomimatsu clearly teaches a transparent container (11), which are windows, and that is imaged on either side of the container. This teaching is the basis for changing the other surface the container of Connelly to be transparent. With respect to claims 23-24, 28-29 and 34-35, Foote clearly suggests a different way to hold a specimen in a specific place for viewing (which is imaging with the eye).

Regarding claim 11, applicant further argues that the teachings of Atwood et al. are inappropriate to one of ordinary skill in the art pertinent to use of a tray for viewing specimens. The examiner respectfully disagrees and points out that the applicant also states on page 12, lines 28-30 of his remarks that the only pertinent discussion is that a sample on a slide is viewed in a conventional manner through a microscope. As a slide can be considered a tray, Atwood et al. is pertinent to use of a tray for viewing specimens and the rejection using Atwood et al. teaching an indicia applied to a tray (figs. 1 and 2) for identification of the specimen disposed therein is appropriate.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lee Fineman whose telephone number is (571) 272-2313. The examiner can normally be reached on Monday - Friday 7:30 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Drew Dunn can be reached on (571) 272-2312. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LAF
April 14, 2004

MARK A. ROBINSON
PRIMARY EXAMINER